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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,709	08/22/2001	Charles A. Morris	1533.0520001	6249

41835 7590 06/21/2007

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EXAMINER	
KISHORE, GOLLAMUDI S	
ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
06/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/933,709	MORRIS ET AL.	
	Examiner	Art Unit	
	Gollamudi S. Kishore, Ph.D	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-44 and 47-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-44 and 47-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment dated 4-11-07 is acknowledged.

Claims included in the prosecution are 18-44 and 47-52.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 22-24, 26-28, 30, 35-44 and 47-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant amends claims 22 and 26 to introduce the upper and lower limits for the fat-soluble vitamin; therefore, the use of the term, 'at least' is improper.

Applicant amends claim 22 to recite 'fat soluble vitamin'; the dependent claim 23 recites B vitamins. These are hydrophilic and not fat soluble vitamins.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 18-44 and 47-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt et al (4,486,435) in combination with Schmidt (4,603, 143)

and Rawlins (4,719,228) or Rawlins in view of Schmidt (4,486,435) or Schmidt (4,719,228) by themselves or in combination.

Schmidt et al. teach a free-flowing, non-agglomerated, non-caking vitamin powder composition comprising about 45 to about 60 percent vitamin, about 2 to about I 8 percent of corn starch, about 0.2 to about 2 percent hydrophobic silica, and other ingredients (col. 8, lines 15-22; col. 5, example 1). Schmidt et al. further teach that the water insoluble carrier can be corn starch (col. 8, line 32). Schmidt et al. also teach that the vitamin can be selected from vitamin H, D, E, K and mixtures thereof as well as vitamin B1, B6, B2, B12, C and mixtures thereof (col. 2, lines 20-34). Lastly, Schmidt et al. teach that the vitamin composition of their invention is suitable for the preparation of tablets (col. 1, line 49). The reference does not specifically discuss stability. However, it is the position of the examiner that absent evidence to the contrary, the formulation must provide appropriate stability, or it would be useless for its intended purpose. What are lacking in Schmidt are the claimed particle sizes of silica.

As discussed before, Schmidt 143 while disclosing free flowing, high density, fat-soluble vitamin powder preparations teaches the use of silica of bigger particle sizes (100 microns). The vitamins include tocopherols, vitamins A, D and K (abstract, col. 2, line 49 through col. 3, line 26, Table 1, Examples and claims).

Rawlins teaches free flowing powders of pharmaceutical agents. According to Rawlins, the silica particles can have a diameters of at lest 10 microns and preferably between 10 microns to 1 mm (abstract, col. 1,lines 48-50; col. 2, lines 24-32; lines 43-

47; Example 2 and claims). Example 2 in particular shows the use of silica of diameter 50 microns (Sipernat 50)

It would have been obvious to use the silica of bigger particle sizes 40-50 microns in the compositions of Schmidt et al 435 or 143 with a reasonable expectation of success, since as evidenced by Rawlins, one can obtain free-flowing powders using silica which has a diameter between 10 microns to 1 millimeter, in particular 50 microns. Although the references are silent with respect to the density and the surface area of the silica particles, since these are commercially available particles and in the absence of showing otherwise and the criticality of these factors, it is the position of the examiner that Rawlins's silica particles which were obtained commercially possess these properties or manipulatable parameters to obtain the best possible results.

Alternately, the use of vitamins D, E or K as the active agents in the compositions of Rawlins who teaches free flowing powders of active agents with silica particles of 50 microns with the expectation of obtaining similar results since the references of Schmidt (435) and (143) each teach that they are free flowing powders of these vitamins can be prepared using silica particles.

Applicant's arugments have been fully considered, but are not persuasive. Applicant argues that the office action has noted that the claims are non-obvious where there is a showing of criticality of the range 40-50 microns for silica and/or the additional physical characteristics of the silica sizes shown to be effective and the results in the declaration of Morris shows that only 40-50 micron range resulted in a free-flowing powder. Further according to applicant, the results are entirely unexpected and that

claims 22 and 26 have been amended to recite the high fat-soluble vitamin loading density, which is achieved unexpectedly. These arguments are not persuasive. First of all, the examiner points out that results presented are not evaluated using scientific measuring parameters to show that the properties are patentably distinct and unexpected. The results such as good, fair, very good, no and yes are merely observations, which are subjective and not scientific (see Table). The last column in the Table merely states, 'acceptance fro processing' with results as 'no' and 'yes'. It is unclear was to what it means. Secondly, according to Rawlins who uses the same Sipernat 50 (50 microns), the powders are free flowing. Third, the results also appear to show that the results depend upon which company the silica is obtained from. For example, Aerosil 200, 12 microns is gritty and Aerosil R 972, 16 microns is very gritty. If increase in sizes produces free flowing powders, then one would assume that 16 micron silica to be better than 12 micron particles. Furthermore, if the particle sizes are that critical and if 50 micron silica shows different results from that of 100, one would expect different or same results with 40 micron particles from those obtained from 50 micron particles. No results are presented for 40-micron particles. Finally, col. 3 shows 'oil absorption'. Among the vitamins, B vitamins, vitamin A, beta-carotene are solids and not oils. Applicant has not shown that the silica particles having solids behave the same way as oily vitamins. Applicant's arguments that a prima facie case of obviousness cannot be established since the cited references do not alone or in combination teach, suggest or motivate one of ordinary skill in the art to arrive at the combination of elements recited in the instant claims are not persuasive since the all the references

teach the use of silica and that of Rawlins in particular teaches the use of silica of particle sizes of 50 microns. Since the upper limit of the vitamins taught Schmidt et al is 60 %, which is closer to instant 65 %, it is deemed obvious to one of ordinary skill in the art to vary the amounts of vitamins to obtain the best possible results. The rejection is maintained.

6. Claims 18-44 and 47-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt et al (4,486,435) in combination with Schmidt (4,603, 143) and Rawlins (4,719,228) or Rawlins in view of Schmidt (4,486,435) or Schmidt (4,719,228) by themselves or in combination as set forth above, further in view of Drake (4,010,073).

The teachings of Schmidt (435), (143) and Rawlins have been discussed above. What is lacking in these references is the teaching that the starch used is a redried starch.

Drake while disclosing free-flowing powders of an enzyme composition teaches that commercial starch generally contains between 10 to 14 % moisture and the resultant product has poor storage stability. Drake further teaches that redried starch with moisture content of 3 % is commercially available and that it increases the storage stability. The compositions of Drake further include silica (abstract, col. 2, lines 29-51, examples and claims).

The use of redried starch instead of starch in the teachings of Schmidt (435), (143) and Rawlins would have been obvious to one of ordinary skill in the art since

Drake teaches high moisture content of regular starch which leads to poor storage stability and hence the use of redried starch.

Applicant's arguments have been fully considered, but are not persuasive. The examiner has already addressed applicant's arugments pertaining to the primary references. Applicant argues that those of ordinary skill in the art recognize that large globular proteins such as enzymes, which are water soluble, and thus, require vastly different formulations than fat soluble vitamins and therefore, Drake reference is not relevant to small hydrophobic molecule formulation chemistry. These arguments are not persuasive since the reference is combined for its teachings of storage stability of redried starch and this would remain the same irrespective what the active agent is. Furthermore, instant claims recite even hydrophilic B vitamins.

3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK